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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/487,312			

EXAMINER	
ART UNIT	PAPER NUMBER
	11

DATE MAILED: 10/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on August 15, 1996.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, ~~whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 17-19, 20-22 ~~is~~/are pending in the application.

Of the above, claim(s) 1, 17-18 ~~is~~/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19, 20-22 is/~~are~~ rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U.S GPO: 1996-410-236/40050

DETAILED ACTION

1. Claims 1 and 17-22 are pending in the instant application. Claim 19 has been amended and claims 20-22 have been newly added. Claims 1 and 17-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 6.

2. The following objections are withdrawn in light of Applicant's amendments:

(1) The objection to claim 19 for depending on a canceled claim.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments filed August 15, 1996 have been fully considered but they are not deemed to be persuasive.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Daniels et al. (U.S. Pat. No. 3,265,579) for the reasons of record as applied to claim 19.

Briefly, the instant claims encompass bovine growth hormone (made recombinantly). Daniels et al. discloses bovine growth hormone which is purified from a tissue source. (See examples 1-6, columns 2-4, especially example 6.) The growth hormone disclosed in the prior art appears to be substantially the same as that of the instant claims. In the event that the bovine growth hormone of the prior art is not exactly the same as the claimed protein, it is noted any slight variation in purity or glycosylation would be obvious to one of ordinary skill in the art at the time the invention was made because it is always desirable to obtain proteins in their most pure form and it was well known in the art that proteins could vary in their glycosylation pattern without altering the activity or function of the protein. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent clear and convincing evidence to the contrary.

Applicant argues that the difference in their bovine growth hormone from that of the prior art is in "the ultimate safety of the product". Applicant provides research articles in support of their position as well as arguments, but this is not deemed persuasive because they are unsubstantiated by facts or evidence of record.

First, the references that were supplied (i.e. see Science, Vol. 228, 1985) speculate that the scrapie virus (which is presumed to be the causative agent in Mad Cow Disease (MCD) and Creutzfeldt-Jakob Disease) may be present in pituitary extracts. However, the very same article also provides support that the virus does not co-purify with growth hormone (see page 1177, column 2, paragraph 2). The bovine growth hormone of the prior art was analyzed by ultracentrifugation and isolated as a single peak, demonstrating a homogeneous composition of bovine growth hormone (column 4, lines 35-37). One of ordinary skill in the art would find it very unlikely that a homogeneous preparation of bovine growth hormone would also contain the virus for MCD. Therefore, one of ordinary skill in the art would not reasonably expect that growth hormone from pituitary tissue extracts to contain the virus for MCD.

Secondly, the claims are directed to bovine growth hormone, whereas the articles presented are directed to human growth hormone. There has never been a reported case of MCD in North America and one of ordinary skill in the art would not expect growth hormone which is isolated from an animal which does not have the virus to contain the virus. It should be noted that the prior art that was cited is from North America, therefore, the bovine growth hormone of the prior art would not be expected to contain the virus that causes MCD.

Thirdly, Applicant states that the difference in the claimed bovine growth hormone lies in the ultimate safety of the product. However, this is an advantages not

disclosed in appellant's application may not be urged as a basis for the allowance of claims, (In re Davies , 177 USPQ 381, 385 (CCPA 1973)) unless the advantage would inherently flow from what was originally disclosed in the specification (In re Zenitz , 142 USPQ 158 (CCPA 1964)). This advantage would not inherently flow from the specification as originally filed because the references cited regarding the scrapie virus and MCD all post-date the filing date of the instant application.

Therefore, Applicant has not rebutted the *prima facie* case of obviousness of the claimed bovine growth hormone. The instant claims are product-by-process claims and the decisional law has clearly emphasized that product-by-process claims are directed to a product and not restrictive to a process because they are not construed as being limited to a product of a specific process (In re Bridgeford, 149 USPQ 55; In re Hirao, 190 USPQ 15). Patentability depends on whether the product is known in the art or obvious and is not governed by its process of production (In re Klug, 142, USPQ 161); therefore, the burden is upon Applicants to establish a patentable difference (In re Fessman, 180 USPQ 324). Further held was that when a prior art product reasonably appears to be the same as the claimed, but differs by the process in which it was produced, a rejection of this nature is eminently fair and the burden is upon appellants to prove, **by comparative evidence**, a patentable difference (In re Brown, 173 USPQ 685; In re Marosi, 218 USPQ 289; In re Thorpe, 227 USPQ 965; In re Fitzgerald, 205 USPQ 594; and as more recently emphasized in Ex parte Gray, 10 USPQ 2d 1922;

Amgen Inc. v. Chugai Pharmaceutical Co., 9 USPQ 2d 1833; and Scripps Clinic v. Genetech Inc., 3 USPQ 2d 1481).

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 4PM.

The fax phone number for this Group is (703) 308-0294. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
October 8, 1996

CA

JOHN ULM
PRIMARY EXAMINER
GROUP 1800